



Re: Questions regarding whether these actions constitute notifications (before I send them in!)

Grigsby, Stacey

to:

ellen.baldassare@lanxess.com

09/08/2017 08:04 AM

Cc:

"Hardy, Jacqueline"

Hide Details

From: "Grigsby, Stacey" <Grigsby.Stacey@epa.gov>

To: "ellen.baldassare@lanxess.com" <ellen.baldassare@lanxess.com>,

Cc: "Hardy, Jacqueline" <Hardy.Jacqueline@epa.gov>

Good morning,

Yes, both label update examples you provide regarding the changes you'd like to make fall under the 98-10 Notification purview.

If you like, you can address your letter to me. Also, as fyi, the Agency timeframe to complete a Notification is 30 days.

Thanks.

From: ellen.baldassare@lanxess.com <ellen.baldassare@lanxess.com>

Sent: Thursday, September 7, 2017 5:35 PM

To: Grigsby, Stacey

Subject: Questions regarding whether these actions constitute notifications (before I send them in!)

Dear Ms. Grigsby-

I am contacting you since I have some questions about a product registered under team 34 I need some help with, I hope I have the right person, feel free to forward this if you have changed to another team. I have a master label with some updates I want to submit to your team for review but before I do so I want to make sure the items would be considered notifications as I can't quite find any examples that directly relate to what I want to do.

First, the more simple change, I have a dilution table that has a typo -- it was updated in 2015 and what should read "1 TBSP" got changed to "2 TBSP". The error was just caught and the product already has the same dilution in the table to make the same concentration of formula with the same volume of water that reads the correct 1TBSP. So I am not requesting a new dilution or use pattern, just correcting an error, is this considered appropriate action by notification?

The second, slightly more complicated change I want to make involves the Storage and Disposal section for a non-household use product. I don't want to directly alter the text prescribed by PRN 2007-4 or the other notices, I want to add language to my labels asking the user to refer to either the leaflet or insert for the full statements---I have a container size where I simply cannot fit the entire pesticide disposal and container disposal statements with all the other required text on the label. For example, instead of the container reading the full "**Pesticide Disposal: Pesticide wastes may be hazardous. Improper disposal.....for guidance**" I want to add the option for it to read "**Pesticide Disposal: Pesticide wastes may be hazardous. Refer to product insert for pesticide disposal instructions.**"

The update will make clear the option to use the shortened version will only be exercised on small containers that also come with an insert denoting full instructions.

While my interpretation of PRN 98-10 and 2007-4 are that these actions both fall within what is acceptable for a notification, I'd like your confirmation of this before I take up the agency and your team's time with a submission.

Thank you for any help you can provide on this matter.

Best Regards/Mit freundlichen Grüßen,

Ellen Baldassare

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